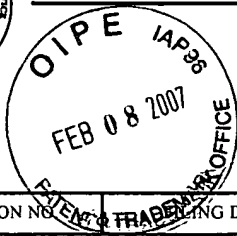




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APPLICATION NO.	MAILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,173	02/18/2004	Gustavo C. Rodriguez	31140C	1808

7590 01/25/2007  
Raymond N. Nimrod  
Roper & Quigg  
Suite 1000  
200 South Michigan Avenue  
Chicago, IL 60604

EXAMINER
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GEMBEH, SHIRLEY V

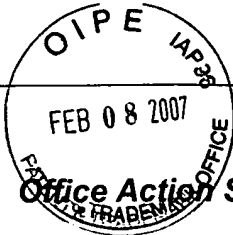
ART UNIT	PAPER NUMBER
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1614

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/25/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.



<b>Office Action Summary</b>	<b>Application No.</b> 10/781,173	<b>Applicant(s)</b> RODRIGUEZ ET AL.	
	<b>Examiner</b> Shirley V. Gembeh	<b>Art Unit</b> 1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.  
2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.  
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 35-90 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.  
6) ☒ Claim(s) 35-90 is/are rejected.  
7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.  
8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.  
10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some \* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)  
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)  
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date (10 sheets)  
4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_  
5) ☐ Notice of Informal Patent Application (PTO-152)  
6) ☐ Other: \_\_\_\_\_

Art Unit: 1614

### **DETAILED ACTION**

The response filed **October 04, 2006** presents remarks and arguments to the office action mailed **June 02, 2006**. Applicants' request for reconsideration of the rejection of claims in the last office action has been considered.

Applicants' arguments, filed, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

#### ***Information Disclosure Statement***

The information disclosure statement (IDS) submitted on 10/10/06 has been received and acknowledged.

#### **Status of claims**

Claims 35-90 are pending.

#### **Preliminary Amendment**

Applicant is advised to look in paragraph 714.01(e) of the MPEP on how to handle preliminary amendment.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Art Unit: 1614

Claims 35-51 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain new subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term less than frequently is a new matter. Specifically, closest to Applicants claim is shown or cited at page 16, lines 24-25, where it recites on a monthly or less than monthly but nothing of less than frequently is taught in the specification. Such a limitation is narrower than what is claimed.

Claims 52-61 and 71-90 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain new subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The term on a periodic basis is not taught. Specifically, closest to Applicants claim is shown or cited at page 16, lines 21, where it recites on a periodic administration but not periodic basis as claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-36, 43-45, 52-54, 61-64, 71-74 and 82-84 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

What is the lower dosage required for vitamin D to effect increase apoptosis?

And the dosage that is required without inducing deleterious hypercalcemic side effect?

***Maintained Claim Rejections - 35 USC § 112-second***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 35-90 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicant argues that a person skilled in the art would understand that the phrase means that the vitamin D compound is not administered on a daily basis.

In response, Examiner disagrees, it is interpreted that less frequently than daily can mean once every other day, once a week, once every other month, once a year or a laundry list of other variation. Simply because there are some medication that are administered once a month, which is less frequently, once a week, once every other month etc. Careful consideration has been given to Applicants remarks but found unpersuasive. Less frequently than daily is very vague and indefinite. A doctor will never tell a patient to take a medication less frequently. There is a time limitation to administering drugs. Once a day is less frequently, as a medication can be administered 4 times a day.

Next, Applicant traversal of receiving vitamin D through sunrays is persuasive and that part of the rejection is withdrawn.

***Double Patenting***

The filing of the terminal disclaimer has been acknowledged by the examiner. The decision of the approval/disapproval is pending therefore the rejection will be maintained until the decision is made.


No claims allowed.

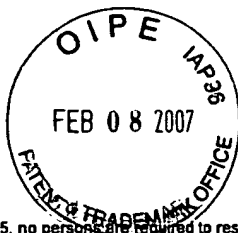
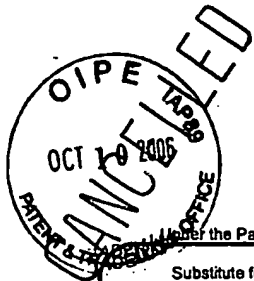
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shirley V. Gembeh whose telephone number is 571-272-8504. The examiner can normally be reached on 8:30 -5:00, Monday- Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel can be reached on 571-272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SVG

  
ARDIN H. MARSCHEL  
SUPERVISORY PATENT EXAMINER



PTO/SB/08A (07-05)  
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## INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use as many sheets as necessary)

Sheet 1 of 10

### Complete if Known

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

U. S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
SG		US- 5,190,935	03-02-1993	Binderup	
		US- 5,206,229	04-27-1993	Calverley	
		US- 5,246,925	09-21-1993	Deluca	
		US- 5,278,155	01-11-1994	Ikekawa	
		US- 5,373,004	12-13-1994	Deluca	
		US- 5,374,629	12-20-1994	Calverley	
		US- 5,380,720	01-10-1995	Deluca	
		US- 5,387,582	02-07-1995	Hansen	
		US- 5,389,622	02-14-1995	Posner	
		US- 5,401,731	03-28-1995	Calverley	
		US- 5,411,949	05-02-1995	Neef	
		US- 5,428,029	06-27-1995	Doran	
		US- 5,446,035	08-29-1995	Neef	
		US- 5,451,574	09-19-1995	Baggiolini	
		US- 5,484,782	01-16-1996	Deluca	
		US- 5,512,554	04-30-1996	Baggiolini	
		US- 5,532,228	07-02-1996	Neef	
		US- 5,536,713	07-16-1996	Deluca	
SG		US- 5,554,599	09-10-1996	Grue-Sorenson	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages Or Relevant Figures Appear	T <sup>3</sup>
		Country Code <sup>4</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)				
SG	.	WO 97/11680	04-03-1997	Elliesen		
SG		WO 98/10771 A1	03-19-1998	Rodriguez		
SG		WO 98/56389	12-17-1998	Rodriguez		

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/781,173
Filing Date	February 18, 2004
First Named Inventor	Rodriguez
Art Unit	1614
Examiner Name	Shirley V. Gembeh
Attorney Docket Number	31140C

Sheet **2** of **10**

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SG		US- 5,716,945	02-10-1998	Grue-Sorensen	
		US- 6,028,064	02-22-2000	Rodriguez	
		US- 6,034,074	03-07-2000	Rodriguez	
		US- 6,310,054	10-30-2001	Rodriguez	
		US- 6,319,911	11-20-2001	Rodriguez	
		US- 6,407,082	06-18-2002	Rodriguez	
		US- 6,444,658	09-03-2002	Rodriguez	
		US- 6,511,970	01-28-2003	Rodriguez	
		US- 6,521,608	02-18-2003	Henner	
		US- 6,765,002	07-20-2004	Rodriguez	
SG		US- 6,977,250	12-20-2005	Rodriguez	
		US- 7,053,074	05-30-2006	Rodriguez	
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		Country Code <sup>4</sup> *Number <sup>5</sup> *Kind Code <sup>6</sup> (if known)				

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Signature

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Date  
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		Examiner Name	Shirley V. Gembeh
Sheet 3 of 10	Attorney Docket Number	31140C	

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SG		BECHTEL, Limitations of pulse oral calcitriol therapy in continuous ambulatory peritoneal dialysis patients, American Journal of Kidney Disease, Feb. 1995, 291-296, 25:2	
		BECKMAN, In vivo regulation of rat intestinal 24-hydroxylase: potential new role of calcitonin, Endocrinology, 1994, 1951-1955, 135:5	
		BEER, A phase I trial of pulse calcitriol in patients with refractory malignancies pulse dosing permits substantial dose escalation, Cancer, June 2001, 2431-2439, 91:12	
		BEER, Beer Abstract, 2002	
		BOWER, Topical calcipotriol treatment in advanced breast cancer, The Lancet, March 2001, 701-702, 337	
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		(cont.) Journal of American College of Nutrition, 1988, 111-118, 7:2	
		BRENNER, Cyclic changes in the primate oviduct and endometrium, Knobil E. Neill JD. eds. The Physiology of Reproduction, 1994, 541-569, 2nd Ed.	
✓		BUCHANAN, The effect of endogenous estrogen fluctuation on metabolism of 25-hydroxyvitamin D, Calcified Tissue International, 1986, 139-144, 39	
SG		BURAS, Vitamin D receptors in breast cancer cells, Breast Cancer Research and Treatment, 1994, 191-202, 31	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
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		Art Unit	1614
		Examiner Name	Shirley V. Gembeh
Sheet 4	of 10	Attorney Docket Number	31140C

NON PATENT LITERATURE DOCUMENTS			
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SG		CARRINO, Proteoglycan synthesis in vitamin D-Deficient Cartilage: Recovery from vitamin D deficiency, Connective Tissue Research, 1989, 135-147, 19	
		CHAPUY, Effect of calcium and cholecalciferol treatment for three years on hip fractures in elderly women, BMJ, April 1984, 1081-1082, 308	
		CHIDA, Inhibition of tumor in mouse skin by 1a, 25-dihydroxyvitamin D3, 1985, Cancer Research, 5426-5430, 45	
		CHRISTAKOS, Vitamin D and Breast Cancer, Diet and Breast Cancer, 1994, 115-118, 12	
		CHRISTOPHERSON, Responsiveness of human carcinoma cells of gynecologic origin to 1,25 dihydroxycholecalciferol, Am. J. Obstet. Gynecol., 1986, 1293-1296, 155:6	
		COHEN, Apoptosis, Immunology Today, 1993, 126-130, 14:3	
		COLLINS, A prospective study to evaluate the dose of vitamin D required to correct low 25-hydroxyvitamin D levels, calcium, and alkaline phosphatase in patients at risk of	
		(cont.) developing antiepileptic drug-induced osteomalacia, Quarterly Journal of Medicine, 1991, 113-122, 78:286	
		COLSTON, 1,25-Dihydroxyvitamin D3 and malignant melanoma: The presence of receptors and inhibition of cell growth in culture, Endocrinology, 1981, 1083-1086, 108	
SG		COOPER, Olestra dose response on fat-soluble and water-soluble nutrients in the pig, American Society for Nutritional Sciences, 1997, 1573S-1588S	

Examiner Signature	/Shirley Gembeh/	Date Considered	01/22/2007
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		Application Number	10/781,173
		Filing Date	February 18, 2004
		First Named Inventor	Rodriguez
		Art Unit	1614
		Examiner Name	Shirley V. Gembeh
Sheet 5	of 10	Attorney Docket Number 31140C	

NON PATENT LITERATURE DOCUMENTS			
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SG		COOPER, Olestera's effect on the status of vitamins A, D and E in the pig can be offset by increasing dietary levels of these vitamins,	
		(cont.) American Society for Nutritional Sciences, 1997, 1589S-1607S	
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		Application Number	10/781,173
		Filing Date	February 18, 2004
		First Named Inventor	Rodriguez
		Art Unit	1614
		Examiner Name	Shirley V. Gembeh
Sheet 6	of 10	Attorney Docket Number	31140C

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SG		GAO, The effects of chemotherapy including cisplatin on vitamin D metabolism, Endocrine Journal, 1993, 737-742, 40:6	
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SG		U.S. Patent Application Ser. No. 11/441,877, filed on May 26, 2006 (Inventor: Roidriguez, et al.)	

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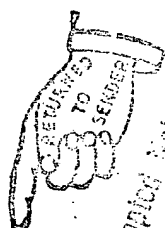
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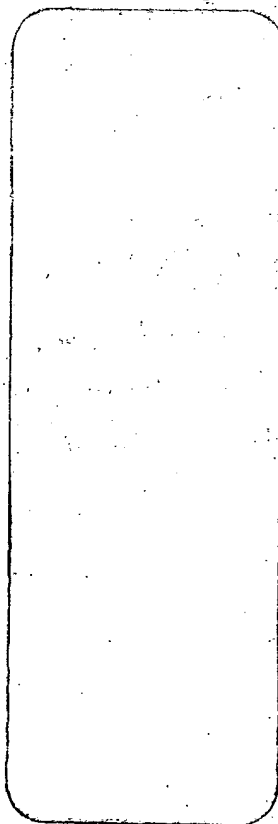
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